K130242
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510(k) Summary

Date of Submission: October 9, 2012

Submitter: nSequence
5420 Kietzke Lane, Suite 205
Reno, NV 89511

Contact Person: Daniel Llop, President/CEO
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Subject Device:
Proprietary Name: Maven Pro
Classification Name: System, Image Processing, Radiological
Regulation: 892.2050
Product Code: LLZ

Predicate Devices:
Name of device *Invivodental*
Manufacturer: Anatomage, Inc.
K number: K070803
Product Code: LLZ

AUG 2 9 2013

Device Description:
Maven Pro Graphic Station is a fully-featured 3D imaging application in medicine. Its unique open architecture and modular framework make customization and integration options trivial. On demand, nSequence will create a fully customized 3D medical imaging solution.

Maven Pro Graphic Station supports all the common 3D medical imaging functionalities used by professional doctors to support their diagnosis. It includes various Volume and IsoSurface rendering, segmentation tools, masking and sculpting, MPR, 2D and 3D measurement and analysis tools. Since 2D imaging is still an important feature, it is possible to switch with a single click to a 2D view, use an even more sophisticated MPR view or switch back to the 3D view.

Maven Pro software is characterized by its intuitive user interface, 2D, MPR and 3D imaging, prime image quality and extensive visualization options, fast image rendering, measurement and analysis tools, and easy integrated reporting.

Intended Uses:
Maven Pro is intended for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a Dental CT scanner. It is also intended for use as a planning and simulation software in the placement of dental implants and surgical treatment.

Risk Analysis Method:
The risk analysis for the device was conducted according to EN ISO 14971:2009.

Summary of Technological Characteristics:
A comparison of the predicate device and Maven Pro shows that many of technological characteristics of the two devices are similar. The differences between the two devices do not raise new questions of safety and effectiveness.

Conclusion:
Maven Pro is substantially equivalent to a legally marketed device. Although it has some technological characteristics that differ from that of predicate, it has the same intended use as the predicate and raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

nSequence
% Rhonda Alexander, MS, MPA
Senior Regulatory Specialist
Registrar Corp
144 Research Drive
HAMPTON VA 23666

Re: K130242
Trade/Device Name: Maven Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 16, 2013
Received: July 17, 2013

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130242

Device Name: Maven Pro

Indications For Use:

Maven Pro is intended for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a Dental CT scanner. It is also intended for use as a planning and simulation software in the placement of dental implants and surgical treatment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)